application. It is respectfully submitted that the outstanding rejections should be withdrawn for the reasons described below

## REJECTION UNDER 35 USC 112

Claims 9 and 10 were rejected under 35 USC 112, second paragraph, as being indefinite. It is respectfully submitted that this rejection is moot in view of the amendment above. As suggested by the USPTO, the phrase "preventing acne" has been replaced by the phrase "reducing the occurrence of". One skilled in the art would readily understand that this phrase encompasses reducing the severity of acne, as well as totally eliminating acne.

Claim 11 has been cancelled, rendering its rejection under 35 USC 112 moot.

## REJECTION UNDER 35 USC 102

Claims 6 and 7 were rejected as being anticipated by either Redmonds I or Redmonds II. Claims 6-8 were rejected as being anticipated by Thorneycroft et al. It is respectfully submitted that these rejections are moot in view of the cancellation of claims 6-8.

## REJECTION UNDER 35 USC 103

Claim 9 remains in the application. It is directed to alleviating acne by administering: 1) a fixed dose of 1 mg of the progestin, norethindrone acetate (NA) in combination with, 2) a gradually increasing dose of the estrogen, ethinyl-estradiol (EE). The EE dose is 20mcg for 5 days, 30mcg for 7 days and 35 mcg for 9 days. Claim 10 depends from claim 9 and is directed to acne vulgaris or cystic acne.

Claims 8-12 (now 9 and 10) were rejected under 35 USC 103 as being obvious over Redmond II and Thorneycroft et al when combined with Schooen and Boissoneault. The gist of the USPTO's rejection is that Redmond II discloses a triphasic oral contraceptive (OC) with a fixed dose of estrogen and a varying dose of progestin that alleviates acne. Thorneycroft et al discloses two OC's that alleviate acne in which each has a fixed dose of estrogen and progestin. Schooen discloses that NA is a progestin. Boissonneault discloses using a fixed dose of NA and a gradually increasing dose of EE to prevent contraception. While the prior art does not teach using a fixed dose of NA and a varying dose of EE to alleviate acne, the USPTO asserts that it would be obvious to use

such a combination in the treatment of acne. It is respectfully submitted that this rejection should be withdrawn for the following reasons.

Redmond II depicts the etiology of acne at page 30S, column 1. As depicted in Figure 2, increased androgen production is the initiating event in the development of acne. On page 30S, at column 2, Redmond explains how OC's alleviate acne. The estrogen component is solely responsible for this anti-acne effect. As explained by Redmond, the estrogen component increases serum levels of SHBG (sex hormone binding globulin). Increased SHBG decreases serum testosterone levels, which in turn decreases sebum production and thereby acne. The progestin component of OC's, while important for birth control, has no beneficial impact upon acne.

Redmond II also explains on page 30S, second column, why a specific OC, Tricyclen, was chosen for the study. Tricyclen contains 35 mcg of ethinyl estradiol(EE). This is the highest dose of EE currently approved in the US. This dose of estrogen would achieve the most significant reduction in free testosterone levels and the greatest impact on acne. Thus to one of ordinary skill in the art, Redmond II teaches that high doses of estrogen should be utilized to alleviate acne.

In addition to discussing the mechanism by which OC alleviates acne, Redmond II summarizes the results of two clinical studies carried out with the high estrogen product. Redmond II does not describe the entry criteria for his subjects, nor does he describe the mean number of acne lesions the patients had at the initiation of the study. He merely reports improvements of up to 50%.

Redmond I, cited by the USPTO in an earlier rejection, does describe the entry criteria for one of the studies described in Redmond II. In Table 2, on page 618, Redmond I provides the mean lesion counts in the control group and the treatment group. Each group had approximately 55 total lesions at the initiation of treatment. In the group receiving OC's, the lesion count dropped to a mean of 35 ( representing a 40% decrease).

As previously noted by the USPTO, claim 9 differs from Redmond I and II due to the reduced dosage of EE. Redmond used a fixed dose of 0.35mcg of EE. By contrast, claim 9 requires lower doses of estrogen. The initial dose of EE is 20 mcg for 5 days, followed by 30 mcg for 7 days, and finally 35mcg for 9 days. As discussed above, Redmond teaches that the anti-acne effects of OC are solely due to the estrogen component. Thus according to the teachings of Redmond, one of ordinary skill in the art would expect that decreasing the dose of estrogen would decrease the beneficial effect which OC's have on acne.

But the data in Applicant's specification shows the opposite. The USPTO's attention is directed to Example 2 of Applicant's specification, pages 28-41, and more specifically to Tables 2 and 3 appearing on pages 32 and 33. The data in Tables 2 and 3 show the lesion counts of the subjects at the beginning of the study and after 6 months of